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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/671,817	09/27/2000	Aled Edwards	11670/2	5923

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EXAMINER

BORIN, MICHAEL L

ART UNIT PAPER NUMBER

1631

DATE MAILED: 03/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/671,817

Applicant(s)

EDWARDS ET AL.

Examiner

Michael Borin

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above claim(s) 4, 6-37, 44-66, 70, 71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 38-43 and 67-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Status of Claims

1. Amendment filed 10/07/2004 is acknowledged. Claims 1, 67-69 are amended. Claims 1-71 are pending. Claims 4,6-37, 44-66,70,71 are withdrawn from consideration. Claims 1-3,5,38-43,67-69 are under consideration.

2. Applicant's arguments are considered and are deemed to be persuasive-in-part. Claims are amended to read on method of determining an unknown biophysical/biochemical property of a target protein by applying to the sequence of the target protein correlation between sequences and biophysical/biochemical properties obtained for other known proteins. Examiner agrees that art rejections of record - which did not address use of such correlations – are moot in view of the amendments. Consequently, rejections not reiterated from previous Office actions are hereby withdrawn and new ground of rejections is applied to the amended claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-3,5,38-43,68,69 are rejected under 35 U.S.C. 103(a) as anticipated by Ladunga et al. in view of Ngan et al.

The instant claim are drawn to method of determining at least one yet unknown biophysical and/or biochemical property of a target protein comprising applying to the sequence of the target protein correlations between sequence information and biophysical/ biochemical properties for proteins with known properties. The protein sequence information, according to specification, p. 6, includes primary amino acid sequence and characteristics which are directly derived from the sequence, including amino acid composition, the character of a region of the sequence, hydrophobicity, charge, molecular weight, the presence and length of low complexity regions and the presence of sequence motifs found in other proteins. Thus, the claims are directed to use of correlation of solubility (elected species) and any of the above sequence information.

Ladunga teaches PHYSEAN method, which stands for PHYsical SEquence ANalysis method, for identification and characterization of protein domains on the basis of physical and chemical properties of amino acids. Ladunga method selects some descriptive biophysical and/or biochemical properties of amino acids (p. 1035, right column), then, for a known polypeptide sequences, determines "weighted property value" over the polypeptide which is expressed as a score - the latter is viewed as a correlation between sequence information and biophysical/biochemical properties of the instant method. p.1031, right column. Then, the "weighted property value" obtained from known polypeptides is applied to sequence of a "target" protein, thus allowing to predict an unknown biophysical and/or biochemical properties for the target protein. See abstract and p. 1032-1033. The descriptive biophysical and/or biochemical properties

are selected from 551 physical, chemical, geometrical and other properties (p. 1035, right column), including hydrophobicity (which is the opposite to “solubility” addressed as one of the properties in the instant claims). PHYSEAN characterizes and predicts proteins with highly variable sequences on the basis of their physical, chemical and biological characteristics and complements methods that require sequence alignments (BLAST, FASTA, dynamic programming) by adding physicochemical information on the protein or the domain (see abstract).

The referenced method does not specifically request “data mining technique” to be used in the method. “Data mining techniques”, according to specification (p. 9) , are computer algorithms and software for identifying relationships between the elements of the database. Merely using a computer to automate a known process does not by itself impart non-obviousness to the invention (see MPEP 2106.VI). Clearly, the referenced method utilizes computer power, and it would be prima facie to use “data mining techniques” known in the art of bioinformatics to correlate properties of amino acids and protein sequence information. For example, various data mining approaches, including Bayesian learning, decision tree analysis, etc are reviewed in Ngan et al. It would be obvious for one skilled in the art of bioinformatics and protein sequence analysis to select an appropriate method of data mining as a part of routine optimization.

Further, the referenced method does not clearly identify “solubility” as one of parameters being assessed. However, the method uses hydrophobicity as one of parameters. Hydrophobicity is opposite to solubility of a protein solution, therefore, it

would be obvious to an artisan to view an estimate of hydrophobicity as an estimate of solubility (or lack thereof) at the same time.

In regard to claim 68, Examiner assumes that protein properties in Ladunga were "examined under uniform conditions" as there is no evidence to the contrary.

In regard to claims 67,69 which specify sources of biochemical/biophysical information (even though claim 67 does not address any source of information about solubility), these limitations do not impart patentability of the claims as the information has to be obtained from some appropriate source (e.g., listed in claim 67), and, in regard to claim 69, obviously, biophysical properties for a given protein will be determined under different conditions than biochemical properties (e.g., solubility vs. protein-protein interaction).

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael Borin, Ph.D.
Primary Examiner
Art Unit 1631

mlb